

# Laparoscopy Compared With Laparoscopically Guided Minilaparotomy for Large Adnexal Masses

## *A Randomized Controlled Trial*

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**OBJECTIVE:** To address the efficacy in terms of intraperitoneal spillage of laparoscopically guided minilaparotomy compared with operative laparoscopy for large adnexal cysts.

**METHODS:** A randomized controlled trial was carried out at a tertiary referral center from January 2005 to September 2006. Sixty eligible patients affected by non-endometriotic adnexal cysts with diameter between 7 and 18 cm were randomly assigned to either operative laparoscopy or laparoscopically guided minilaparotomy.

**RESULTS:** The relative risk for intraperitoneal spillage among women treated with laparoscopy was 5.55 (95% confidence interval 1.88–16.33). Operative times were significantly shorter in patients who underwent laparoscopically guided minilaparotomy. Surgical difficulty was significantly higher in patients treated with laparoscopy. However, postoperative stay was shorter.

**CONCLUSION:** Laparoscopically guided minilaparotomy, when compared with laparoscopy, is able to reduce intraperitoneal spillage in patients with presumably benign large adnexal masses, with minimal increase in patient short- and long-term discomfort. Because data regarding the importance of intraperitoneal spillage during surgery for benign and malignant pathologies, as well as rupture rates during traditional laparotomy, are scarce, traditional laparotomy still represents the standard treatment. In women desiring a

minimally invasive strategy for large cysts, laparoscopically guided minilaparotomy should be considered.

**CLINICAL TRIAL REGISTRATION:** Australian Clinical Trials Registry, [www.actr.org.au](http://www.actr.org.au), ACTRN012607000241437 (*Obstet Gynecol* 2007;110:241–8)

**LEVEL OF EVIDENCE: I**

The safety and efficacy of operative laparoscopy in the management of benign adnexal cysts has been amply demonstrated, and this surgical approach has become the most widely adopted treatment for this clinical condition.<sup>1,2</sup> However, large adnexal masses represent a dilemma for endoscopic surgeons since, the bigger the diameter, the greater the technical problems, operative times, and probability of unexpected malignancy.<sup>3–5</sup>

In several centers, large ovarian cysts are directly managed by conventional laparotomy with consequent postoperative morbidity and anti-esthetic results; others suggest that, with a proper selection, the size of an ovarian cyst does not constitute an absolute contraindication for laparoscopy.<sup>6</sup> Indeed, a major concern with laparoscopic management of large adnexal masses is the possibility of intraperitoneal spillage of an unexpected malignant cyst.

Previous randomized controlled trials comparing laparoscopy and minilaparotomy<sup>7,8</sup> in the management of ovarian cysts concluded that operative laparoscopy is the best approach for the management of adnexal cysts but that minilaparotomy can be considered an acceptable minimally invasive approach yielding similar results.

The objective of the present study was to assess if laparoscopically guided minilaparotomy could reduce the rupture rate of conventional operative lapa-

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### **Financial Disclosure**

*The authors have no potential conflicts of interest to disclose.*

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ISSN: 0029-7844/07



roscopy for the treatment of large nonendometriotic ovarian cysts with no other risk factor for malignancy other than size.

## MATERIALS AND METHODS

The purpose of the present trial was to compare minimally invasive standard surgery (laparoscopy) and an alternative minimally invasive surgical strategy (laparoscopically guided minilaparotomy) in patients affected by large, apparently benign, nonendometriotic adnexal cysts. The primary outcome was set as uncontrolled cyst spillage and/or rupture rate. Secondary endpoints were surgical difficulty, operative and postoperative results, short- and long-term complications, and short-term patient satisfaction.

Institutional review board approval was obtained from Dipartimento Assistenziale Integrato of Obstetrics and Gynecology, Azienda Policlinico Umberto I. Consecutive patients referred to the gynecologic departments of the Universities of Rome La Sapienza and Campus Bio-Medico with a diagnosis of monolateral large adnexal cysts were evaluated for enrollment in the present study.

Inclusion criteria were age between 18 and 45 years, largest cyst diameter between 7 and 18 cm, no ultrasonographic suspicion of endometriosis or malignancy (thick papillary projections, solid areas, central flow, and velocimetric features of high velocity and low resistance<sup>9</sup>), serum CA125 within normal range, body mass index below 29 kg/m<sup>2</sup>, American Society of Anesthesiologists' physical status classification class 0–2, no acute or chronic pelvic known disease, no sign of acute abdomen, no previous laparotomies, no requirement of other associated surgical procedures, possibility of placing an intrauterine manipulator, and signed informed consent to the surgical procedure and to traditional surgical staging in case of unexpected malignancy. Patients with a contralateral cyst with greatest diameter larger than 7 cm were considered ineligible for the study.

On hospital admission, 1 day before surgery, all patients were submitted to transabdominal and transvaginal ultrasonography to confirm the diagnosis of apparently benign adnexal mass. At this point an ultrasonographic estimate of cyst size was carried out. No mechanical bowel preparation was performed.<sup>10</sup> Antibiotic prophylaxis was carried out with intravenous cefalotin 2 g before surgery 30 minutes before incision, and antithrombotic prophylaxis was carried out with low-molecular-weight subcutaneous heparin 2 hours before surgery and until complete mobilization. All women were submitted to diagnostic open laparoscopy and, at the end of this procedure, randomly

assigned to either operative laparoscopy (group A) or laparoscopically guided minilaparotomy (group B). Randomization was carried out before the introduction of accessory ports using blind envelopes kept in the operative theater. The randomization technique is described below. Postoperative intravenous fluid administration (2,000 mL) for the first 24 postoperative hours was standard. Patients were advised not to drink for at least 12 postoperative hours. Metoclopramide 20 mg was provided to reduce postoperative nausea. Omeprazole 20 mg was administered for 7 postoperative days for stress–gastritis prophylaxis.

Procedures were performed under general endotracheal anesthesia. All procedures were carried out by senior gynecologists specialized in traditional and endoscopic surgery. A Foley catheter and a uterine manipulator were placed before the beginning of the diagnostic laparoscopy. Open laparoscopy was carried out to access the abdominal cavity, with an incision of approximately 1.2–1.5 cm at the level of umbilical area. A 10-mm port for the laparoscope was inserted through the umbilicus. Pneumoperitoneum was carried out. The pelvis and abdomen were carefully explored to exclude signs of unexpected malignancy. Peritoneal washing was carried before the beginning of the operative procedure. Adhesiolysis was performed, when indicated, to reestablish the physiological abdominal and pelvic anatomy. These procedures were carried out either through accessory ports or through the minilaparotomy incision.

In the laparoscopy group (Group A), three additional 5-mm ports were inserted under direct vision at the level of lower abdominal quadrants and sovrappubic region. The patient was then placed in Trendelenburg position. The plane of cleavage of the cyst was located with the aid of grasping forceps, and the cyst capsule was separated from the ovarian cortex using diverging tractions. All efforts were carried out to avoid spontaneous rupture of the cyst. The ancillary port in the sovrappubic region was enlarged to fit a 10-mm trocar for the insertion of an endobag. Whenever possible, the unruptured cyst was placed inside the endobag to contain extraperitoneal spillage. Under direct view, controlled cyst aspiration was carried out for unruptured cysts that did not directly fit within the endobag. Hemostasis was achieved with bipolar coagulation. The ovarian incision was left open. The peritoneal cavity was copiously rinsed with Ringer's lactate solution. Ringer's lactate solution (1,000 mL) was left in the peritoneal cavity for adhesion prevention.<sup>11</sup> Intraoperative frozen section of the cyst specimen was routinely performed. The fascia was closed in the two 10-mm trocar insertion



sites with slowly absorbable, monofilament suture. The skin was closed with simple stitches in non absorbable, monofilament suture.

In the laparoscopically guided minilaparotomy group (Group B), a 3- to 7-cm transverse skin incision 1 to 2 cm below the pubic hair line and 2 to 4 cm above the pubic symphysis was carried out at surgeon's discretion on the basis of the laparoscopic finding. A stitch is placed at the margins of the incision and removed at the end of the procedure to minimize the risk of skin laceration due to traction of the retractors. The subcutaneous fat was incised in a cranial direction, and the abdominal fascia opened transversely 2–3 cm above the skin incision to a width of 10–16 cm. This allows for an adequate surgical field. The patient was placed in Trendelenburg position and the bowel packed upward with warm, wet pads. Two or three hand-held Deaver retractors were used throughout the procedure and maneuvered in one direction to avoid countertraction and optimize intraoperative view. When possible, the cyst was delivered outside the abdomen through the incision. When size did not allow delivery or in case of cyst rupture, the cyst content was aspirated, and the cyst wall rupture site controlled with a clamp. All efforts were made to minimize intraperitoneal spillage. Excision of the ovarian cyst was performed in the standard fashion and the ovarian edges approximated with a suture stitch avoiding the ovarian cortex. Hemostasis was achieved with bipolar coagulation. The peritoneal cavity was copiously rinsed with Ringer's lactate solution. Ringer's lactate solution (1,000 mL) was left in the peritoneal cavity for adhesion prevention.<sup>11</sup> Intraoperative frozen section of the cyst specimen was routinely performed. The fascia was closed in the trocar insertion site and in the minilaparotomy incision with continuous suture using a delayed absorbable, monofilament suture. A rapidly absorbable subcutaneous suture was used. The skin was closed with a nonabsorbable subcuticular suture. Subcutaneous drains were left in place until drainage was less than 20 mL for 24 hours.<sup>12</sup>

A list of measurements and definitions used in the study is contained in the Box, "Measurements and Definitions."

A formal sample size calculation was performed using as the primary outcome uncontrolled cyst spillage. The sample size utilized (28 compared with 28 observations) was selected to detect, with 80% power at the 0.05 alpha level, a difference of 40% in rupture rate given a reference rate of approximately 80% for patients treated with operative laparoscopy, reported in our previous study.<sup>8</sup>

## Measurements and Definitions

*Consumption of analgesic:* patients' request for analgesics (ketorolac 30 mg intravenously) before hospital discharge.

*Esthetic results:* visual analogue scale assessment reported by the patient at 3 months follow-up "How unattractive would you judge your scars?" (0 optimal, 10 unattractive).

*Intraoperative and postoperative complications:* complications occurring between randomization and four weeks after surgery or hospital discharge.<sup>13</sup>

*Mobilization recovery:* interval between return to the gynecologic ward and ability to be fully mobile around the ward in hours as reported by the patient.

*Recovery of bowel movement:* interval between return to the gynecologic ward and first passage of flatus in hours as reported by the patient.

*Postoperative pain:* visual analogue scale assessment reported by the patient at 6, 12 and 24 hours postoperatively: "How would you estimate the intensity of the pain you feel?" (0 no pain, 10 very intense pain).

*Postoperative stay:* interval between surgery and hospital discharge in days. Within these departments, hospital discharge is carried out only between 8:00 AM and 1:00 pm.

*Scar size:* length of longest scar measured postoperatively (including the umbilical scar) with a sterile ruler after having sutured the surgical breach.

*Surgical difficulty:* visual analogue scale assessment reported by the surgeon at the end of the operative procedure: "How challenging was this procedure?" (0 very easy, 10 very difficult).

*Surgical time:* interval between random assignment and skin closure in minutes.

*Uncontrolled cyst spillage and/or rupture:* rupture occurring during cyst mobilization or after cyst aspiration with significant intraperitoneal spillage outside the endobag; minimal fluid contamination of the peritoneal cavity deriving from the aspiration breach is also considered as spillage.

A computerized randomization list was independently generated for the choice of the surgical strategy (Group A laparoscopy, Group B laparoscopically guided minilaparotomy). Treatment arms were written and enclosed in sequentially numbered sealed envelopes by a third party. The envelopes were opened in the operative theater after the patient had been enrolled and after diagnostic laparoscopy.

Due to the low likelihood of achieving a normal



distribution for variables analyzed in this study, the Central Limit Theorem was not invoked and non-parametric tests were applied for statistical analyses. Data are therefore presented as medians and percentiles. Statistical evaluation was performed with the  $\chi^2$  test or the Fisher exact test, where appropriate, for categorical variables, and the Mann Whitney for continuous variables. When  $\chi^2$  test was used, Yates continuity correction was always adopted. Statistical significance was set at a *P* value of  $<.05$ .

## RESULTS

From January 2005 to September 2006, 177 patients were referred to our institution for the treatment of adnexal mass. Sixty-two patients were excluded from further investigation for the trial because ultrasonographic cyst size measurement was below 7.0 cm or above 18.0 cm. An additional 44 women were not included for clinical and/or ultrasonographic characteristics other than size. A total of 71 patients were considered eligible for the trial before diagnostic laparoscopy. During diagnostic laparoscopy, a further 11 patients were excluded before random assignment. In eight patients, surgical field was considered inadequate by the surgeon, and for patient safety a traditional laparotomy was preferred; whereas in three patients, peritoneal signs of malignancy were identified during diagnostic laparoscopy. At the end of diagnostic laparoscopy, a total of 60 patients were randomly assigned with a ratio 1:1 to laparoscopy (group A) or laparoscopically guided minilaparotomy (group B). Six patients in group A were not treated according to protocol. In three, one, and two patients a conversion to laparoscopically guided minilaparotomy, Pfannenstiel, and a low vertical incision were carried out. Five conversions were carried out for technical difficulty, whereas in the remaining case, conversion was carried out after operative laparoscopy because of frozen section diagnosis of ovarian cancer. Two patients in group B were not treated according to protocol. In both cases, conversion was carried out through an increase of the transverse cutaneous incision because of technical difficulties. A flow diagram of study subjects is illustrated in Figure 1.

Three months postoperatively, all patients were reevaluated with a general and pelvic examination. At this point, follow-up was considered closed for the study.

The patient and cyst characteristics are reported in Table 1. Intention to treat data and analyses are reported in Table 2. Median operative time was 81 (range 45–124) minutes and 47 (range 32–84) minutes ( $P<.001$ ) for groups A and B, respectively. Median postoperative hemoglobin levels were 12.1 (9.9–13.6)

g/dL and 11.6 (10.0–13.4) g/dL ( $P$ =not significant) for groups A and B, respectively. Median operative difficulty was 7.4 (range 4.2–9.4) and 4.9 (1.8–8.4) ( $P<.001$ ) for groups A and B, respectively. Uncontrolled spillage occurred in 87% (21 of 24) and 29% (8 of 28) ( $P<.001$ ) of patients in groups A and B, respectively. The relative risk of cyst rupture among women subjected to operative laparoscopy compared with those treated with laparoscopically guided minilaparotomy was 5.55 (95% confidence interval 1.88–16.33). No major perioperative complications occurred during the trial. Postoperative ileus and fever of unknown origin were the most frequently reported complications. Median length of scar was 2.3 (1.2–4.2) cm and 3.8 (3.0–6.8) cm ( $P<.001$ ) in groups A and B, respectively. Fifty percent (12 of 24) and 64% (18 of 28) ( $P$ =not significant) of patients in groups A and B, respectively, required additional analgesia. Pain after 6 hours was significantly higher in group B. At 12 and 24 hours postoperatively, no significant difference in pain scores were identified. Postoperative interval to first flatus was significantly longer in group B. Time to mobilization was similar between groups. Median postoperative stay was 1 (range 1–3) days and 1 (range 1–5) days ( $P<.05$ ) in group A and B, respectively. Postoperative esthetic damage was generally felt mild in both groups but patients treated with laparoscopy had significantly lower “esthetic damage” visual analog scale scores compared to patients treated with laparoscopically guided minilaparotomy (median score 0.7, 1.9; for patients in groups A and B respectively;  $P<.001$ ).

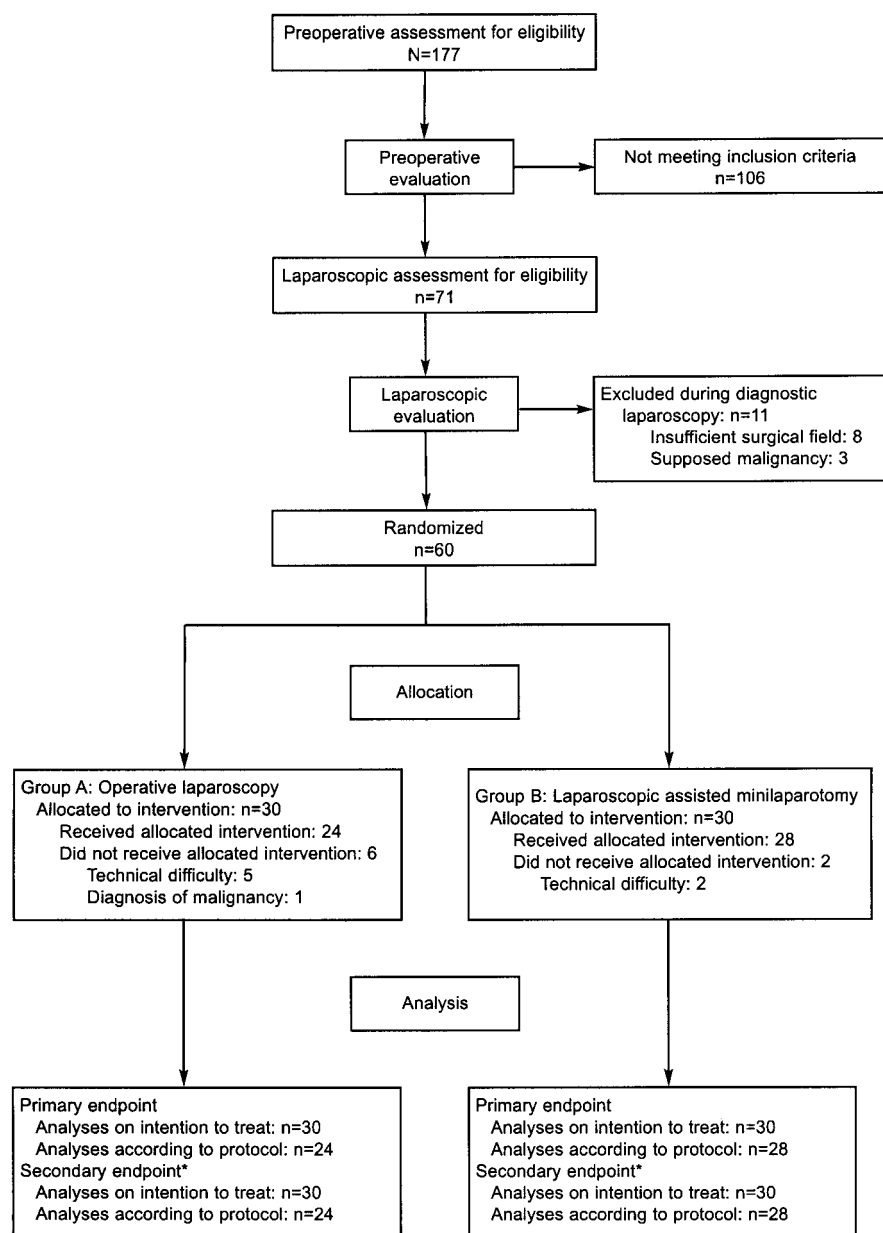
## DISCUSSION

Laparoscopy is widely adopted and has become the standard treatment in patients affected by supposed benign adnexal masses in several centers worldwide.<sup>14–15</sup> Laparoscopy in patients with benign ovarian tumors has been demonstrated to be associated with better surgical and economic outcomes and shorter recovery times.<sup>15</sup> However, several issues regarding this surgical approach and the possible detrimental effect on prognosis of patients with unexpected ovarian malignancy remain unresolved.<sup>15</sup> Modern preoperative screening<sup>17</sup> and diagnostic algorithms<sup>9,18–20</sup> are constantly improving and being developed, but the risk of encountering an unexpected ovarian malignancy is estimated to be between 0.9% and 13%.<sup>21</sup>

The primary concern is that, in patients with unrecognized neoplasms, laparoscopy may be associated with an increase in the rate of intraperitoneal spillage with consequent dissemination of tumor cells and advance in disease stage.<sup>22–24</sup> Furthermore, intra-







**Fig. 1.** Patient's flowchart. \* Intention-to-treat analyses were not carried out regarding pain and analgesic consumption.  
*Benedetti Panici. Laparoscopy and Laparoscopic Minilaparotomy. Obstet Gynecol 2007.*

**Table 1.** Patient Characteristics (Intention-to-Treat Analyses)

	Group A Laparoscopy (n=30)	Group B Laparoscopically Guided Minilaparotomy (n=30)	P
Age (y)	31 (24–36)	29 (24–35)	.67
Body mass index (kg/m <sup>2</sup> )	23 (22–25)	23 (21–24)	.36
Cyst size (cm)	8.4 (8.0–12.2)	8.2 (7.9–10.4)	.33
Ultrasonographic diagnosis			.95
Mucinous	12	13	
Serous	10	9	
Dermoid	8	8	
Bilateral cysts	6	4	.77

Data are presented as median value (25–75 percentile) or n.



**Table 2. Operative Data (Intention-to-Treat Analyses)**

	Group A Laparoscopy (n=30)	Group B Laparoscopically Guided Minilaparotomy (n=30)	P
Operative time (min)	85 (75–110)	48 (44–52)	<.001
Preoperative Hb level (g/dL)	13.0 (12.3–13.6)	13.3 (12.5–13.6)	.34
Postoperative Hb level (g/dL)	12.1 (11.1–12.8)	11.4 (11.0–12.1)	.06
Uncontrolled spillage	24	10	<.001
Scar size (cm)	2.6 (1.8–3.2)	4.0 (3.4–4.6)	<.001
Time to first flatus (h)	22 (18–26)	28 (23–36)	<.001
Time to mobilization (h)	21 (16–24)	21 (19–24)	.35
Postoperative stay (days)	1.0 (1.0–2.0)	1.5 (1.0–1.8)	.14

Hb, hemoglobin.

Data are presented as median value (25–75 percentile) or n.

peritoneal spillage of a benign cyst might be the cause of severe clinical conditions, such as chemical peritonitis. Unfortunately, since spillage became a major physician concern only after the introduction of laparoscopy into routine clinical practice, data regarding spillage during conventional laparotomy are scarce and underestimation of cyst rupture rates reported by retrospective studies is likely.

Minilaparotomy has been proposed for the surgical treatment of apparently benign gynecologic conditions as an alternative minimally invasive strategy.<sup>25</sup> Recent studies have demonstrated that minilaparotomy can be safely adopted for a variety of surgical procedures in women with benign<sup>8,26–29</sup> and malignant<sup>30,31</sup> conditions.

Two independent Italian randomized trials<sup>32,33</sup> investigated the possibility of using minilaparotomy for treatment of apparently benign adnexal masses. Fanfani et al<sup>32</sup> observed significantly longer operating times in patients subjected to laparoscopy, but postoperative ileus was longer in patients who had minilaparotomy. In a trial previously carried out by our group,<sup>33</sup> we observed a significant increase in minor postoperative complications and an increase in immediate postoperative discomfort using minilaparotomy compared with laparoscopy. However, an exploratory analysis carried out during the trial highlighted a significant decrease in intraperitoneal spillage in patients treated with minilaparotomy for large cysts (above 7 cm in size) compared with laparoscopy.

The management of large adnexal masses still represents a treatment dilemma for gynecologists. Generally, even in the best referral centers, large adnexal masses are treated by laparotomy<sup>34–36</sup> to minimize the risk of rupture of an unexpected malignancy<sup>37–39</sup> or for technical difficulties. Recently, some authors have advocated the use of laparoscopy for the management of large adnexal cysts. Salem<sup>40</sup> reported the management of 15 cases of cysts reaching above

the level of the umbilicus treated by laparoscopy. Cysts were removed by stripping after having performed laparoscopically guided cyst aspiration. Median operative time was 55 minutes. Sagiv et al<sup>41</sup> reported 21 cases of large cysts with a median cyst volume of 2,000 mL treated by cyst aspiration, followed by cystectomy or adnexectomy by laparoscopy. Goh et al<sup>42</sup> reported four cases with median cyst greatest diameter of 21 cm. Cysts were removed outside the peritoneal cavity after having performed laparoscopically guided cyst aspiration. One patient required postoperative blood transfusions.

The primary objective of the present trial was to compare the results in terms of spillage rates in patients affected by large adnexal masses and treated with two different surgical techniques. This trial confirms that large ovarian cysts can be treated with minimally invasive techniques. Our data demonstrate that laparoscopically guided minilaparotomy is associated with reduced, uncontrolled peritoneal spillage but is associated with an increase in postoperative discomfort and recovery time compared with operative laparoscopy. Spillage was chosen as primary endpoint because it is probably the greatest concern for gynecologic surgeons<sup>43</sup> due to its prognostic significance.<sup>44</sup> Preliminary diagnostic laparoscopy was added to traditional minilaparotomy because it allows an inspection of the whole abdomen and upper abdominal implants or external adnexal vegetations, therefore reducing the risk of unrecognized ovarian cancers. Furthermore, it aids the surgeon in the choice of where and how large the minilaparotomy incision is to be made. In addition, laparoscopy is considered in our centers a fundamental step in the management of patients affected by ovarian cancer.<sup>45</sup>

Although it is not possible to carry out precise comparisons between the results obtained in the present and previously reported studies, results in the laparoscopy group appear consistent with those re-



ported by previous authors.<sup>40–42</sup> Negligible differences in operative times,<sup>40</sup> blood loss, and minor operative complications<sup>42</sup> can probably be ascribed to differences in patient's characteristics, surgical techniques, or differences in the definitions adopted. Patient satisfaction was very high with this technique.

As highlighted by the observations of some authors<sup>37,38</sup> regarding the most frequent malignant nature of large ovarian cysts compared with benign ones, the safest approach to large cysts should always attempt to minimize spillage. This principle of safety has to be tailored to the modern patient, physician, and social requirements of using, whenever possible, the least aggressive surgical approach. In our opinion, laparoscopically guided minilaparotomy, with the possibility of frozen section analyses and of an adequate surgical staging in case of unexpected ovarian malignancy, might represent a reasonable balance between safety and general needs in patients with large ovarian cysts.

In conclusion, laparoscopically guided minilaparotomy, when compared with laparoscopy, is able to reduce intraperitoneal spillage in patients affected by presumably benign, large adnexal masses, with minimal increase in patient short- and long-term discomfort. Since data regarding the importance of intraperitoneal spillage during surgery for benign and malignant pathologies, as well as rupture rates during traditional laparotomy, are still scarce, traditional laparotomy still represents the gold standard treatment. In patients that desire a minimally invasive strategy, after careful counseling and in appropriate settings, laparoscopically guided minilaparotomy can be considered a safe minimally invasive choice.

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